

**13 December 2016**  
**[31–16]**

## **Call for submissions – Application A1123**

### **Isomalto-oligosaccharide as a Novel Food**

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FSANZ has assessed an Application made by Essence Group Pty Ltd via FJ Fleming Food Consulting Pty Ltd to permit isomalto-oligosaccharide as a novel food to be used as an alternative (lower calorie) sweetener and bulk filler in a range of foods and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 3 February 2017**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

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## Supporting documents

The [following documents](#)<sup>1</sup> which informed the assessment of this Application are available on the FSANZ website:

- SD1 Risk and technical assessment
- SD2 Assessment against Forum Policy Guidelines

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<sup>1</sup> <http://www.foodstandards.gov.au/code/applications/Pages/A1123IMOasaNovelFood.aspx>

## Executive summary

Essence Group Pty Ltd has submitted an Application seeking approval of isomalto-oligosaccharide (IMO) as a novel food for use as an alternative (lower calorie) sweetener and as a bulk filler. The Applicant seeks to market IMO in a number of food categories including carbonated beverages, sports and energy drinks, soy milks, milk-based drinks, milk-based and non-milk-based meal replacement drinks, fruit juices, fruit-flavoured drinks, meal replacement bars, breakfast bars and confectionery at levels up to 15 g IMO/serving. The Applicant did not request a specific energy factor for IMO.

IMO is a mixture of short-chain carbohydrates, manufactured from starch and contains both digestible and non-digestible saccharides. The Applicant notes the relative sweetness of IMO as approximately 60% that of sucrose and the energy value as 6.3 kJ/g (1.5 kcal/g). As well as commercial manufacture, IMO occurs naturally in fermented foods such as rice, miso, soy sauce, and sake; it is approved in a number of overseas jurisdictions including USA, Canada and Europe.

The Advisory Committee on Novel Foods<sup>2</sup> (ACNF) previously considered that IMO does not have a history of consumption in Australia and New Zealand and as such, meets the definition of non-traditional food in the Australia New Zealand Food Standards Code (the Code). Therefore, as a new food ingredient, IMO requires a safety assessment prior to approval for use in Australia and New Zealand.

FSANZ's assessment concluded that IMO meets the stated purposes of a bulk filler when used as an ingredient to replace sucrose in food. Also, according to the Applicant's reported composition and FSANZ's proposed specification for IMO, it would be a sweetener with less sugars compared to sucrose. According to nutrition labelling requirements, the content of IMO's monosaccharides and disaccharides, as well as its available and unavailable carbohydrate contents would need to be known by the manufacturer.

IMO has a history of safe use in humans in countries other than Australia and New Zealand and is well tolerated i.e. no abdominal symptoms (e.g. laxative effects) in healthy humans up to a single daily dose of 40 g. In the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is considered appropriate. However, it is anticipated that IMO will be poorly tolerated by individuals with congenital or acquired sucrase-isomaltase deficiency.

The estimated mean dietary exposures to IMO (assuming 50% replacement of added sugars) in the proposed list of foods and also in all foods except infant formula products, infant foods and formulated supplementary foods for young children, were below 40 g/day for all population groups assessed. Estimated dietary exposure to IMO for some high consumers may exceed 40 g/day of IMO; however exposure is likely to be considerably over-estimated due to assumptions made in the calculations.

Therefore FSANZ proposes to permit IMO as a novel food, and to extend the Applicant's proposed list of foods to nearly all foods except infant formula products, infant foods and formulated supplementary foods for young children, and not to impose a limit/serving. We consider that broadening the permission would not pose a risk to healthy individuals. Generic labelling requirements would apply to provide consumers with information on the presence of IMO in food to enable informed choice. Additional information will be prepared for health professionals who support individuals with sucrase-isomaltase deficiency.

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<sup>2</sup> <http://www.foodstandards.gov.au/industry/novel/novelrecls/pages/default.aspx>

# 1 Introduction

The Application is seeking approval of isomalto-oligosaccharide (IMO) as a novel food, specifically as a bulk filler and an alternative sweetener. A separate energy factor for IMO was not sought.

IMO is manufactured from starch and is a mixture of short-chain carbohydrates based on glucose and is predominantly linked by  $\alpha$  1→6 linkages. It contains both digestible and non-digestible saccharides. The Applicant notes the relative sweetness of IMO is approximately 60% that of sucrose and the energy value as 6.3 kJ/g (1.5 kcal/g). As well as commercial manufacture, IMO occurs naturally in fermented foods, such as rice miso, soy sauce, and sake.

A previous Application A578 – Isomaltulose as a Novel Food<sup>3</sup>, was approved by FSANZ in 2007. Some aspects of A578 are relevant to this Application and have been considered in the assessment. Isomaltulose is a disaccharide of glucose and fructose linked by the same  $\alpha$ -D-(1,6) linkages as IMO.

## 1.1 The Applicant

Essence Group Pty Ltd is an Australian-based importer of specialty food ingredients and provides tailored consultation services to clients to assist with new product development and innovation.

## 1.2 The Application

The Application seeks an amendment to Schedule 25 – Permitted novel foods at levels up to 15 g IMO/serving. The amendment would permit the sale and use of IMO as a food ingredient in Australia and New Zealand. Essence Group has applied to market IMO (powder) as an alternative (lower calorie) sweetener and bulk filler in a number of food categories including carbonated beverages, sports and energy drinks, soy milks, milk-based drinks, milk-based and non-milk-based meal replacement drinks, fruit juices, fruit-flavoured drinks, meal replacement bars, breakfast bars and confectionery at levels up to 15 g IMO/serving. The specific list of foods requested is available in supporting document 1 (SD1). The Applicant does not intend that formulated supplementary food for young children or foods for infants contain IMO<sup>4</sup>.

The Applicant states that IMO can be used as:

- an alternative to other carbohydrate bulk sweeteners such as sucrose, glucose, fructose and high fructose or maltose syrups
- an alternative filler to provide bulk and texture to other currently available food ingredients, such as fructo-oligosaccharides (FOS), inulin, polydextrose and dextrins.

At the theoretical maximum sugar replacement level, IMO is likely to be used as a part of a blend of currently permitted sweeteners rather than used alone.

The Applicant further states the intention not to market or support the use of IMO as a prebiotic, or to make nutrition content claims or general level health claims.

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<sup>3</sup> See <http://www.foodstandards.gov.au/code/applications/Pages/applicationa578isoma3297.aspx>

<sup>4</sup> FSANZ has taken the Applicant's description of "foods for infants" to include infant formula products.

The Applicant also notes that, to support a nutrition content claim about dietary fibre, the product would need to meet relevant requirements of the Code i.e. meet the definition of dietary fibre in Standard 1.2.8 – Nutrition information requirements; meet requirements relating to making nutrition content claims in Standard 1.2.7 – Nutrition, health and related claims and in Schedule 4 – Nutrition, health and related claims, using the methods of analysis in Schedule 11 – Calculation of values for nutrition information panels. No additional method of analysis for dietary fibre was requested.

## **1.3 Current standards**

### **1.3.1 Australia and New Zealand**

Standard 1.5.1 – Novel foods permits the sale of novel foods that have had a pre-market assessment and approval by FSANZ. These permissions are listed in Schedule 25.

A ‘novel food’ is defined in the Code as a ‘non-traditional food’ that requires an assessment of public health and safety considerations having regard to [a number of matters which are set out in the definition]. Therefore, a novel food must first be considered to be a ‘non-traditional’ food which is also defined in the Code and includes a food that does not have a history of human consumption in Australia or New Zealand.

Specifications in Schedule 3 – Identity and purity, and the calculation of values for nutrition information panels in Schedule 11 are also relevant to this Application.

### **1.3.2 International**

IMO is permitted in a number of overseas jurisdictions:

- USA – IMO has FDA Generally Recognized as Safe (GRAS) status (GRAS GRN 246) for a list of foods similar to the Applicant’s request.
- Canada – in 2009, Health Canada had no objection to the use of IMO as a food ingredient.
- UK/EU – IMO was permitted to be placed on the EU market in July 2013 (as a novel food).
- Japan – IMO has been on the FOSHU (Food for Specified Health Uses) ingredient list for more than 10 years.
- China has a National Standard for IMO – GB/T 20881 – 2007.
- Korea – oligosaccharides are listed under section 10 of Article 5: Standards and Specifications for Each Food Product of the Food Code.

## **1.4 Reasons for accepting application**

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that (a) might be developed as a food regulatory measure; or (b) warranted the variation of a food regulatory measure.

Amending the Code as requested would permit the sale and use of IMO as a novel food ingredient in Australia and New Zealand.

## **1.5 Procedure for assessment**

The Application is being assessed under the General Procedure.

## **2 Summary of the assessment**

### **2.1 Risk and technical assessment**

FSANZ conducted a risk assessment on the request to permit IMO as a novel food for use as a bulk filler and alternative sweetener in a range of foods. The full assessment is provided at SD1 which contains a food technology report, a hazard assessment and a dietary exposure assessment.

The food technology assessment concluded that when IMO is used as an ingredient to replace sucrose in a food, it meets the stated purpose of a bulk filler and, according to the Applicant's reported composition of IMO and FSANZ's proposed specification, it would be a sweetener with less sugars in comparison to sucrose.

IMO has a history of safe use in humans in countries other than Australia and New Zealand. IMO is not efficiently converted to glucose in the small intestine so the majority (~60–70%) of the ingested IMO is likely to pass unchanged into the colon. There is no evidence of adverse gastro-intestinal effects (e.g. diarrhoea) in healthy humans up to a single daily dose of 40 g. Also, IMO did not cause any abdominal symptoms (e.g. laxative effects) in any subjects at this level. In the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is considered appropriate. However, it is anticipated that IMO will be poorly tolerated by individuals with congenital or acquired sucrase-isomaltase deficiency.

A chronic dietary exposure assessment was not required due to the ADI of 'not specified' being assigned. The dietary exposure assessment (DEA) therefore focused on a more acute or short term exposure and assessed two separate scenarios using consumption data (for day 1 only) from the most recent national nutrition survey for Australia. The first scenario was based on IMO replacing 50% added sugars gram for gram in only those foods requested by the Applicant; and the second scenario on IMO replacing 50% of added sugars gram for gram in all foods (excluding infant formula products, infant foods and formulated supplementary foods for young children). The estimated dietary exposures were compared to levels of IMO reported to be well tolerated in the literature i.e. a single dose (40 g) of IMO.

For both scenarios for all population groups assessed, the estimated mean dietary exposures to IMO were <40 g IMO. For nearly all foods (scenario 2) which assumed that every such food in every food category replaced 50% of added sugars with IMO (worst case), some high consumers of IMO may exceed 40 g/day of IMO, however the dietary exposure is likely to be considerably over-estimated due to assumptions made in the calculations.

In conclusion, IMO is considered safe and suitable to be added to the food supply noting that consideration was not given to IMO addition to infant formula products, infant foods and formulated supplementary foods for young children.

### **2.2 Risk management**

In addition to the outcomes of the risk and technical assessment, the following points have been considered in determining relevant risk management strategies.

#### **2.2.1 Novelty**

The ACNF has previously (2011, 2012) considered that IMO does not have a history of consumption in Australia and New Zealand. Therefore, it meets the Code definition of 'non-traditional food' and, as a new food ingredient, requires a safety assessment prior to approval for use in Australia and New Zealand.

It is also noted that novel food ingredients that can perform a technological function in a food. If approved, IMO would be added to Schedule 25.

### **2.2.2 Nutrition implications for use of IMO as an alternative sweetener**

The Applicant proposes the use of IMO as an alternative sweetener and although not applying for a specific energy factor in the Code, considers the energy value to be 6.3 kJ/g (1.5 kcal/g). For comparison, Health Canada<sup>5</sup> considered the caloric (energy) value for IMO under their consideration to be 2.4 kcal/g. FSANZ also notes that the UKFSA determined that there was not enough evidence to show that IMO under their consideration had a significantly reduced energy content compared with other digestible carbohydrates (UKFSA 2012).

The Applicant's IMO preparation consists of 20–43% monosaccharides and disaccharides (SD1). We note that Health Canada considers that the IMO was composed of 15–20% of smaller saccharides and 70–80% larger oligosaccharides. Typically, IMOs are glucose oligomers with predominantly  $\alpha$ -D-(1, 6) glycosidic linkages. Some of the  $\alpha$ -D-(1, 6) linked fractions will be digested in the small intestine and absorbed as glucose. However, the majority (~60–70%) of the ingested IMO would likely pass unchanged into the colon (SD1). Carbohydrates that pass into the colon contribute less energy than those fully digested in the small intestine.

The nutrition labelling of IMO is discussed in section 2.2.4.3.

### **2.2.3 Foods permitted addition of IMO**

Based on the risk assessment conclusions, FSANZ considers it appropriate to extend the requested list of foods that may contain added IMO to nearly all foods except infant formula products (Standard 2.9.1)<sup>6</sup>, food for infants (Standard 2.9.2) and formulated supplementary foods for young children (Standard 2.9.3, Division 4) and not to impose a limit/serving.

FSANZ considers that broadening the permission would not pose a risk to population health and safety, given the absence of a health based guidance value. The mean estimated IMO intakes for all persons arising from 50% replacement of added sugars in nearly all foods were below the well tolerated level of 40 g single dose.

Although dietary exposure estimates indicate that some high use individuals may exceed this level, these estimates are not likely to be realistic for the vast majority of the population because it was assumed *all* foods that contain added sugars in a given food category contain IMO at 50% replacement, which is a worst case scenario. It is noted that the Applicant suggests that no more than 2 foods/day containing IMO would be consumed. As an example, to obtain more than 40 g IMO from a single food would require consumption of 890 mL of an energy drink or 1050 mL of flavoured milk (Appendix 6, SD1).

FSANZ also notes that Health Canada's exposure assessment considers that it is unlikely that all food will contain IMO, and that a consumer would buy all the food products containing IMO, and that all IMO food bought would be consumed together.

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<sup>5</sup> Health Canada – Novel food information – Isomalto-oligosaccharide (Vitasugar), Appendix 7 of A1123 or <http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/isomalto-oligosaccharide-eng.php>

<sup>6</sup> Since the Applicant indicated no intention for formulated supplementary food for young children or foods for infants to contain added IMO, FSANZ has taken "foods for infants" to include infant formula products.

Based on Canadian market penetration, the actual dietary exposure to IMO is expected to be approximately 10% (estimated market share of IMO in the market generally) of the maximum estimated percentile exposure. Furthermore, no effects were reported at the 40 g single bolus dose level which FSANZ has used as the best available benchmark for considering risk management options for this Application.

## **2.2.4 Labelling of food products with added IMO**

The addition of IMO to food will be subject to a number of existing generic labelling requirements in the Code which FSANZ considers would provide adequate information to enable consumers to make informed choices. FSANZ has not identified a need to develop additional labelling measures specifically for the use of IMO.

### **2.2.4.1 Statement of ingredients**

Standard 1.2.4 – Information requirements – statement of ingredients, requires food for sale to be labelled with a statement of ingredients unless exempt. Should manufacturers choose to add IMO to a food, IMO will need to be included in the statement of ingredients and listed using a name by which the ingredient is commonly known; or a name that describes its true nature (e.g. ‘isomalto-oligosaccharide’). These requirements will be particularly important for those individuals with congenital or acquired sucrase-isomaltase deficiency, for whom IMO would be poorly tolerated (also see section 2.3.1).

### **2.2.4.2 Mandatory advisory statements and declarations**

#### *Allergen declarations*

IMO can be produced using starch obtained from wheat, barley or oats. Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations requires that certain substances be declared if they are present in the food, including cereals containing gluten i.e. wheat, oats, barley, rye and their hybrids. Therefore, Standard 1.2.3 requirements would apply to products containing IMO.

#### *Advisory statement on laxative effects*

Standard 1.2.3 also requires that foods containing certain substances (primarily polyols) above a threshold level (10 g/100 g or 25 g/100 g depending on the substance) must display a statement to the effect that excess consumption can produce laxative effects.

This requirement was based on evidence that demonstrated laxative effects in humans from a single bolus dose of either 10 g or 25 g of the substance<sup>7</sup>. If evidence showed that no laxative effects occurred with the consumption of the substance, then it was determined that a statement about possible laxative effects need not apply to that substance.

The need for a statement about possible laxative effects was also considered during Application A578 – Isomaltulose as a Novel Food<sup>3</sup>. Evidence showed that there were no adverse effects in human volunteers with doses up to 50 g/day. It was determined that the use of a laxative effects statement was not warranted for the use of isomaltulose in a food.

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<sup>7</sup> This labelling advisory statement resulted from FSANZ’s assessment of Proposal P202 in 1999 (not available on the FSANZ website).

Based on the risk assessment (SD1), FSANZ is not proposing to apply an advisory statement on laxative effects to the use of IMO. This is consistent with the approach taken in Proposal P202 – Review of Provisions for Low Joule Foods & Carbohydrate-modified Foods and Application A578.

### **2.2.4.3 Nutrition information – contribution of IMO to carbohydrate and energy content declarations**

Standard 1.2.8 – Nutrition information requirements requires that the sugars content be listed separately from the total carbohydrate content in the nutrition information panel (NIP). The definition of ‘sugars’ in Standard 1.1.2 – Definitions used throughout the Code, includes all types of monosaccharides and disaccharides, including those that may be resistant to digestion in the small intestine. As such, the monosaccharide and disaccharide components (20–43%) of the Applicant’s IMO preparation are defined as ‘sugars’, and would contribute to a food’s declared sugars content in its NIP.

The total carbohydrate content in the NIP is calculated using section S11—3 (Calculation of values for nutrition information panel)<sup>8</sup>. Based on these calculations, the **available** carbohydrate component of IMO will need to be displayed in the NIP unless it is calculated by difference<sup>9</sup>, since the definition of ‘carbohydrate’ in Standard 1.1.2 refers to available carbohydrate. In relation to IMO, the available carbohydrate component would depend on its proportion of ‘available’ sugars and oligosaccharides. The Code does not specifically define ‘available’ sugars etc. or ‘unavailable carbohydrate’ or provide any categorisation of individual food ingredients into ‘available’ or ‘unavailable’ groups.

The range of carbohydrates in IMO will influence how total energy contents are declared in the NIP on product labels. Schedule 11 lists several energy factors (for determining a food’s total energy content) for different types of carbohydrates. Assigned energy factors for the general components—available carbohydrates and unavailable carbohydrates—are 17 kJ/g and 8 kJ/g respectively. The energy contribution of IMO will depend on the proportions of its composition considered to be available or unavailable carbohydrate (as discussed above) given that the Applicant has not requested a specific energy factor for IMO. FSANZ therefore has not assessed the energy value of IMO. However, food enforcement authorities may have a view on what energy factor would apply.

Based on the above considerations, a food manufacturer will need to know the monosaccharide and disaccharide content, and also the available and unavailable carbohydrate contents of the IMO ingredient to meet the requirements for displaying the sugars, carbohydrate and energy contents on the label of a food containing IMO. A manufacturer should have access to this information, as Standard 1.2.1 – Requirements to have labels or otherwise provide information, requires that the purchaser (of IMO) must be provided with any information they request as necessary to enable them to comply with labelling requirements.

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<sup>8</sup> Standard 1.1.2 refers to section S11—3 in respect of the definition of ‘carbohydrate’ (which is also defined as ‘available carbohydrate’ or ‘available carbohydrate by difference’). This section states that available carbohydrate is calculated by summing the average quantity in the food of total available sugars and starch, and any available oligosaccharides, glycogen and maltodextrins (if they are quantified or added to the food). Alternatively, available carbohydrate can be calculated by difference. This calculation involves subtracting from 100 the average quantity in the food (expressed as a percentage) of water, protein, fat, dietary fibre, ash, alcohol, any other unavailable carbohydrate, and a substance listed in subsection S11—2(3).

<sup>9</sup> If the available carbohydrate is calculated by difference, the unavailable carbohydrate component is also required to be declared in the NIP.

#### **2.2.4.4 Nutrition and health claims**

The Applicant has indicated that IMO will be marketed as a lower calorie replacement for sugar (sucrose).

If a food manufacturer intends to make nutrition or health claims about the energy or sugar/s content of products containing IMO, then these foods will need to meet the requirements in Standard 1.2.7. The specific criteria for making energy and sugar/s content claims are in Schedule 4 – Nutrition, health and related claims.

#### **2.2.4.5 Glycaemic response**

The Advisory Committee on Novel Foods and Processes of the United Kingdom Food Standards Agency (UKFSA) has assessed the literature on IMO (UKFSA, 2012), and considers that IMO has a similar glycaemic response to glucose. On this basis, the UKFSA has approved the use of IMO, but only on the condition that there is a statement on the label of a food containing IMO indicating that it is not suitable for diabetics (UKFSA, 2013). The reason given for the statement is that individuals with diabetes may perceive IMO to be a prebiotic dietary fibre rather than a mixture of carbohydrates that may have an impact on blood glucose levels.

FSANZ considers that the glycaemic response to foods is highly variable and depends greatly on the food matrix, rather than the presence of a single ingredient. Other ingredients could also moderate a food's glycaemic response despite the presence of IMO. Therefore a mandatory labelling statement in relation to diabetes is not proposed.

#### **2.2.5 Specifications for IMO**

Standard 1.3.4 – Identity and purity regulates the identity and purity of substances. Standard 1.3.4 adopts specifications for food additives and other substances in foods by reference to specific sources, including specifications established by JECFA. If a suitable specification is not included in these sources, Standard 1.3.4 provides distinct specifications for some ingredients and substances.

IMO is not covered by a specification identified in Standard 1.3.4 or in any of the primary or secondary specification sources approved for use by FSANZ. Therefore, FSANZ has prepared a detailed specification as provided in SD1. This is included in the drafting (see Attachment A).

#### **2.2.6 Analytical methods for analysis**

There are analytical methods available that can separate and analyse the individual oligosaccharides in the IMO preparation. High performance liquid chromatography (HPLC) is the analytical method of choice. The Application contains a HPLC analytical method (Appendix 14 of the Application).

### **2.3 Risk communication**

#### **2.3.1 Consultation**

Consultation is a key part of FSANZ's standards development process. All calls for submissions for this Application will be notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News.

Subscribers and interested parties are also notified via email. In addition, targeted communication with relevant health professional networks will occur to ensure that patients with sucrose-isomaltase deficiency are informed.

The Applicant and submitters will be notified at each stage of the assessment. Every submission on an application is reviewed by FSANZ staff and the Board, who prepare a response to those issues. While not all comments may be taken up during the process, they contribute to the rigour of our assessment.

### **2.3.2 World Trade Organization (WTO)**

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

Amending the Code to include permissions for IMO would have a trade enabling effect as it would permit IMO to be sold in Australia and New Zealand and also allow imports into Australia and New Zealand and sold, where currently they are prohibited. However, this is not expected to have a significant effect on trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade Agreement was not considered necessary.

## **2.4 FSANZ Act assessment requirements**

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

### **2.4.1 Section 29**

#### **2.4.1.1 Consideration of costs and benefits**

In June 2016, the OBPR advised<sup>10</sup> that, based on the information provided, the Application appears to be machinery in nature and will not have adverse impacts on business, community organisations or individuals. Therefore, a Regulation Impact Statement (RIS) is not required.

However, FSANZ has considered the costs and benefits of the regulatory options for the purposes of section 29.

This is not intended to be an exhaustive, quantitative economic analysis and, in fact, most of the impacts that are considered cannot easily be assigned a dollar value. Rather, the assessment considers the qualitative impacts of each option, deliberately limited to broad areas such as trade, consumer information and compliance.

In reaching its decision to prepare a draft variation, FSANZ considered two options:

*Option 1:* Prepare a draft variation to the Code to permit the use of IMO as a novel food in all foods except infant formula products, infant foods, and formulated supplementary food for young children.

*Option 2* Reject the Application.

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<sup>10</sup> OBPR ID 20966

*For Option 1:*

- Consumers may benefit as foods containing IMO would provide an alternative sweetener on the market, possibly with a preferred taste profile. Additional products may become available due to the availability of IMO for Australian and New Zealand food manufacturers, and the access to imported food products containing IMO that are currently manufactured overseas.
- Food manufacturers would have an alternative bulk sweetener available which could provide an opportunity to reformulate or develop new products. Any increased costs would be a business decision based on expected returns.
- Government enforcement agencies may have some costs to validate the analytical method of analysis for IMO, and if they choose to analyse for the presence of this sweetener.
- Given the voluntary nature of the addition of IMO, its addition will occur only if there is demand from consumers because of the enhanced attributes of the product (taste, cost or health) or other benefits (technological or cost) to be obtained by manufacturers. No harms or costs have been associated or identified with consumption of IMO for most consumers. However, individuals with sucrose-isomaltase deficiency will not gain any potential benefit from the use of IMO in foods.

*For Option 2:*

Any benefits identified above would be lost through maintaining the status quo.

In conclusion, FSANZ considers that the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application are highly likely to outweigh the costs to the community, government or industry that would arise from the development or variation of the food regulatory measure. A net benefit, or at the very worst a neutral outcome will be achieved if this Application is approved. However, feedback from submitters is welcome.

**Questions for submitters:**

1. What are the potential costs and/or benefits of the proposed risk management options to you as a stakeholder?
2. Are there other costs or benefits that should be considered?
3. Do you consider that the benefits of progressing with approving this Application outweigh the costs?
4. If you have any data or information to support your view, FSANZ would welcome the opportunity to consider the information.
5. Are there other affected parties that have not been identified that should be contacted?

**2.4.1.2 Other measures**

There are no other measures (available to FSANZ or not) that would be more cost-effective than a regulatory measure developed or varied as a result of the Application.

**2.4.1.3 Any relevant New Zealand standards**

All affected standards are joint Australia New Zealand standards. There are no other relevant New Zealand standards.

#### **2.4.1.4 Any other relevant matters**

Other relevant matters are considered below.

#### **2.4.2 Subsection 18(1)**

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

##### **2.4.2.1 Protection of public health and safety**

FSANZ concludes that approval of IMO as a novel food as proposed above, does not pose a risk to human health for Australian or New Zealand consumers. The generic labelling requirements (section 2.2.4) would provide information on the presence of IMO for individuals with sucrose-isomaltase deficiency. In addition, a communication strategy is planned (section 2.3.1) to provide information to health professionals likely to manage these individuals.

##### **2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

The generic labelling requirements for IMO-containing foods will provide adequate information for consumers to make informed purchase decisions

##### **2.4.2.3 The prevention of misleading or deceptive conduct**

No issues have been identified. As IMO will be marketed as an alternative replacement for sugars (mostly sucrose), the generic labelling requirements for provision of nutrition information and voluntary nutrition and health claims prevent misleading or deceptive conduct.

#### **2.4.3 Subsection 18(2) considerations**

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has evaluated the best available scientific evidence, and concluded that there are no scientific data that indicates a potential safety or nutritional concern for people consuming IMO as proposed above (SD1).

- **the promotion of consistency between domestic and international food standards**

Internationally, IMO is recognised in a number of jurisdictions (section 1.3.2) and the proposed approach would promote consistency with such approvals.

- **the desirability of an efficient and internationally competitive food industry**

Approval of IMO may increase the international competitiveness of Australian and New Zealand business by potentially gaining access to overseas markets. The proposed change will ensure that IMOs approved for use in trading partner countries and foods containing IMO can be imported into Australia and New Zealand, providing Code requirements are met.

- **the promotion of fair trading in food**

No issues have been identified.

- **any written policy guidelines formulated by the Forum on Food Regulation**

There are [two guidelines](#)<sup>11</sup> that relate to IMO:

- Policy Guideline on Novel Foods
- Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals.

FSANZ's assessment against these policy guidelines is provided at SD2.

### **3 Draft variations**

The draft variation to the revised Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

### **4 References**

UKFSA (2012). Initial Opinion: Isomalto-oligosaccharide as a novel food ingredient; and UKFSA (2013). Isomalto-oligosaccharide as a novel food ingredient, (accessed 22 July 2016) <https://acnfp.food.gov.uk/committee/acnfp/assess/fullapplies/Isomalto-oligosaccharide>.

### **Attachments**

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

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<sup>11</sup> <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

## Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



### Food Standards (Application A1123 – Isomalto-oligosaccharide as a Novel Food) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer  
Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

## 1 Name

This instrument is the *Food Standards (Application A1123 – Isomalto-oligosaccharide as a Novel Food) Variation*.

## 2 Variation to a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

## 3 Commencement

The variation commences on the date of gazettal.

### Schedule

#### [1] Schedule 3 is varied by

[1.1] inserting into the table to subsection S3—2(2), in alphabetical order

isomalto-oligosaccharide section S3—36

[1.2] inserting after section S3—35

#### S3—36 Specification for isomalto-oligosaccharide

For isomalto-oligosaccharide (IMO), the specifications are the following:

- (a) chemical structure—IMO is a mixture of glucose oligomers with  $\alpha$  1→6 glycosidic linkages that include isomaltose, panose, isomaltotriose, isomaltopentaose and various branched oligosaccharides;
- (b) description—a white crystalline powder or transparent clear pale yellow coloured syrup;
- (c) IMO content (dry weight)—not less than 96% (powder) and not less than 75% (syrup);
- (d) oligosaccharides—not less than 55% with a degree of polymerisation of 3 or more;
- (e) glucose (dry weight)—not more than 5%;
- (f) moisture—not more than 4% for the powder, not applicable for syrup;
- (g) ash (dry weight)—not more than 0.3%.

#### [2] Schedule 25 is varied by inserting into the table to section S25—2, in alphabetical order

isomalto-oligosaccharide

Must not be added to:

- (a) infant formula products; and
- (b) food for infants; and
- (c) formulated supplementary food for young children.

## **Attachment B – Draft Explanatory Statement**

### **1. Authority**

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1123 which seeks to permit isomalto-oligosaccharide as a novel food to be used as an alternative sweetener and bulk filler in a range of foods. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

### **2. Purpose**

Isomalto-oligosaccharide is currently not permitted in the Code. Therefore, the draft variation will amend section S25—2 in Schedule 25 to provide a permission for isomalto-oligosaccharide to be used in food, except for infant formula products, infant food and formulated supplementary foods for young children. The draft variation will also amend Schedule 3 to provide specifications for the identity and purity of isomalto-oligosaccharide.

### **3. Documents incorporated by reference**

The variations to food regulatory measures do not incorporate any documents by reference.

### **4. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1123 will include one round of public consultation following an assessment and the preparation of a draft variation.

A Regulation Impact Statement (RIS) was not required because the proposed variation is likely to have a minor impact on business and individuals and is deemed to be deregulatory in nature (see OBPR ID 20966).

### **5. Statement of compatibility with human rights**

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

### **6. Variation**

Item [1] varies Schedule 3. Subitem [1.1] amends the table to subsection S3—2(2) by inserting a reference to isomalto-oligosaccharide and to proposed section S3—36. Subitem [1.2] inserts proposed section S3—36. The proposed subsection sets specifications for the identity and purity of isomalto-oligosaccharide for the purposes of section 1.1.1—15.

Item [2] varies Schedule 25 by inserting a reference to and conditions for isomalto-oligosaccharide into the table to section S25—2. The conditions prohibit the addition of isomalto-oligosaccharide to infant formula products (Standard 2.9.1), food for infants (Standard 2.9.2) and formulated supplementary food for young children (Standard 2.9.3 Division 4). The effect of the amendment is to provide a permission for isomalto-oligosaccharide as a novel food for the purposes of section 1.1.1—10. The permission is for food (other than infant formula products, food for infants or formulated supplementary food for young children) to consist of isomalto-oligosaccharide or have isomalto-oligosaccharide as an ingredient.